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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/916, 140	08/21/97	SCOTT	M SUV-003.04

<input type="checkbox"/>	HM12/0908	<input type="checkbox"/>	EXAMINER
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1632 *10*

**DATE MAILED:** 09/08/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No. <b>08/916,140</b>	Applicant(s) <b>Scott et al.</b>
	Examiner <b>Richard Schnizer</b>	Group Art Unit <b>1632</b>

Responsive to communication(s) filed on Aug 4, 1999

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 1-49 is/are pending in the application.

Of the above, claim(s) 1-48 is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 49 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

- received.
- received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 6

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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### **DETAILED ACTION**

Applicant's election with traverse of group VI, claim 49 in Paper No. 9 is acknowledged. The traversal is on the ground(s) that no undue search burden is placed on the examiner. This is not found persuasive because the inventions are distinct for the reasons given in the restriction requirement, they comprise divergent subject matter necessitating separate non-coextensive searches, and they fall under different classifications.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-49 are pending in the application, claims 1-48 have been withdrawn from consideration by the examiner, and claim 49 is under consideration in this Office Action.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

#### ***Written Description***

Claim 49 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Applicant is referred to the interim guidelines on written description published June 15, 1998 in the Federal Register, Volume 63 Number 114, pp. 32639-32645 (also available at [www.uspto.gov](http://www.uspto.gov)).

Claim 49 is a method of treating an animal by administering an “agent” which complements a loss of function mutation of *patched*. The specification defines such agents on page 19, lines 16-31. Thus, claim 49 is drawn to the genus comprising organic molecules between the sizes of 50 and 2500 Daltons. In analyzing whether the written description requirement is met for genus claims, it is first determined whether a representative number of species has been described by complete structure. If this criterion is met, it is then determined whether a representative number of species has been described by other relevant identifying characteristics. In this particular case, Applicant briefly describes the structural limitation that the agent should be able to bind proteins (page 19, lines 24-27), as well as general methods of screening for such small molecules (paragraph bridging pages 19 and 20). However, no molecule which complements a loss of *patched* function is described in the specification by **complete** structure. This disclosure is insufficient to convey to a skilled artisan that Applicant was in possession of any species of the claimed genus at the time of filing. Thus the written description requirement is not satisfied.

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***Enablement***

Claim 49 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Enablement is considered in view of the *Wands* factors (MPEP 2164.01(a)).

*Nature of the invention.* Claim 49 is drawn to a method of treating an animal having a disorder characterized by a loss of function of a *patched* gene. The method comprises administering an agent which inhibits derepression of one or more *patched*-dependent genes. Thus the agent should function as a *patched* protein functional mimic.

*Breadth of the claim.* The claim is broad, being drawn to treatment of any disorder characterized by a loss of *patched* function, with any effective organic molecule between 50 and 2500 Daltons in mass.

*State of the prior art.* The prior art offers no suggestion or teaching of any molecule which could serve as a *patched* protein mimic, particularly a molecule between 50 and 2500 Daltons. At the time of filing, hedgehog protein was the only known ligand for *patched* protein. Hedgehog is a signaling protein which binds to the extracellular domain of *patched*. Thus at the time of filing, there was no known intracellular ligand of *patched*, and the signaling pathway from *patched* protein to the nucleus had not been resolved. Therefore, there were no structurally-identified candidate molecules for *patched* protein mimics.

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*Guidance and exemplification in the specification.* The specification briefly describes some potential structural characteristics of an effective agent, such as the ability to bind proteins. However, no specific structure is described, and no specific protein target is identified. The specification also considers delivery of the agent (page 22, lines 24-32, to page 23, line 3), but no information concerning dosage or treatment schedule is given. That is, no actual method of treatment is described, and no exemplification is given.

*Predictability in the art.* At the time of filing there were no known patched functional mimics, and the patched signal transduction pathway had not been elucidated. The predictability of finding a patched structural mimic under these circumstances, and developing a successful method of treatment using it, are deemed low.

*Amount of experimentation necessary.* A skilled artisan would have had to perform an excessive amount of experimentation in order to first discover a functional mimic for patched protein between 50 and 2500 Daltons in mass, and then to develop a successful treatment protocol for any disease related to patched loss of function.

In view of the lack of guidance and exemplification concerning candidate molecules and treatment protocols, as well as the state of the art with respect to these topics, a skilled artisan would have had to perform undue experimentation in order to practice the invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim 49 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: any steps in the method of treatment. Method claims need not recite all operating details but should at least recite positive, active steps so that the claims will set out and circumscribe a particular area with a reasonable degree of precision and particularity. In general, claims should make clear the subject matter which is encompassed, and the subject matter from which others are precluded. *Ex parte Erlich*, 3 USPQ2d 1011 at 6.

### ***Conclusion***

The claim is not allowed, but it is free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 703-306-5441.

The examiner can normally be reached Monday-Friday from 7:30 to 4:00 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Stanton, can be reached at 703-308-2801. The FAX phone number for art unit 1632 is 703-308-0294.

Inquiries of a general nature or relating to the status of the application should be directed to the group receptionist whose telephone number is 703-308-0196.

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Richard Schnizer, Ph. D.

*Bruce Campbell*

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PRIMARY EXAMINER  
GROUP 1800